IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

JOSHUA WILSON, et al., ***Plaintiffs*,** **v.** **LLOYD AUSTIN, *et al.*,** ***Defendants.***	No. 4:22-cv-438 ALM

MOTION FOR RECONSIDERATION OF COURT'S GRANT OF DEFENDANTS' MOTION TO DISMISS (ECF 61)

Plaintiffs in the above-captioned action file this Motion for Reconsideration under FRCP 59(e) in light of the Fifth Circuit Court of Appeals' decision in *Apter v. Dep't of Health & Hum. Servs.,* No. 22-40802, 2023 WL 5664191 (5th Cir. Sept. 1, 2023), and its application to Plaintiffs' claims against both the Defendant Department of Defense ("DoD") and the identical Defendant as in *Apter*, officials from the Food and Drug Administration ("FDA"). In its order issued September 1, 2023 ("September 1 Order"), ECF 61, this Court granted the Defendants' Motion to Dismiss all of the Plaintiffs' claims as moot. This Court did not have the benefit of the *Apter* decision and the Fifth Circuit's explication of the doctrines of both statutory and common law *ultra vires* claims, and therefore it could not have applied that law to Counts III-VIII of the Plaintiffs' First Amended Complaint (ECF 41, ¶¶ 198 - 283), which plead *ultra vires* and APA claims against the final actions of officials from Defendant DoD and Defendant FDA. For the reasons set forth below, Plaintiffs respectfully move this honorable Court to reconsider its previous ruling in light of the intervening change in law between the time this Court wrote and published its decision granting the Defendants' Motion to Dismiss and when the *Apter* decision was handed down by the Fifth Circuit.

Plaintiffs seek reconsideration only with respect to Counts III and IV (statutory and non-statutory *ultra vires* claims against DoD for Interchangeability Directives); Count V (APA claim against DoD Interchangeability Directives; Count VI (statutory and non-statutory *ultra vires* claims against FDA Interchangeability Directives); Count VII (APA claim against FDA waivers of enforcement of statutory mandates); and Count VIII (*ultra vires* claim against FDA waivers).

LEGAL STANDARDS

A Rule 59(e) motion for reconsideration may be granted where there is: "(1) an intervening change in controlling law; (2) the availability of new evidence not previously available; and (3) the need to correct a clear error of law or fact or to prevent a manifest injustice." *Brown v. Mississippi Co-op Extension Serv.*, 89 F. App'x 437, 439 (5th Cir. 2004) (*citing Schiller v. Physicians Res. Grp. Inc.*, 342 F.3d 563, 567 (5th Cir. 2003)).

STATEMENT OF THE CASE

The named Plaintiffs in this case are military members who, in their First Amended Complaint, sought review of the actions of both DoD and FDA officials. Specifically, after setting forth the factual predicate for their claims, Plaintiffs sought review in this Court of two sets of distinct, but related, agency actions that exceeded the statutory authority of the officials who issued them. ECF 41, ¶¶ 198-283. These *ultra vires* actions are: (1) the DoD's Interchangeability Directives, (2) the FDA's Interchangeability Guidance in its Emergency Use Authorization ("EUA") letters, and (3) the FDA Waivers of mandatory, non-waivable statutory informed consent and labeling requirements. *Id.* Further, each named Plaintiff alleged that the Defendant DoD took adverse administrative and disciplinary actions against them, up to and including the discharge of named plaintiff Steven Brown, on the basis of these *ultra vires* actions. *See, e.g.*, ECF 49 at 17-18

(discussion of SSG Brown's punishment for refusing to take EUA-only, unlicensed vaccine while in Germany). *See also* ECF 49-2, 49-3, 49-4.

Plaintiffs challenged the entire array of DoD Interchangeability Directives as *ultra vires* actions: "None of these officials and officers of the United States had any authority to mandate unlicensed EUA products… Accordingly, each of these officials acted *ultra vires*. The Military Defendants' officials and officers of the United have acted without any lawful authority whatsoever, and without any colorable basis for the exercise of authority." ECF 41, ¶¶ 223 - 225. The plaintiffs also alleged that their injuries were a direct result of these *ultra vires* acts. Id., ¶¶ 227 -228. The principal action, however, that sat at the top, was the September 14, 2021 Memorandum of an official within the Department of Defense, Ms. Terry Adirim, the Assistant Secretary for Defense and Health Affairs, who made the declaration that an unlicensed, Emergency Use Approved (EUA) biologic product was "interchangeable with" – and could be used "as if" it were – a fully-licensed, but unavailable product, and could therefore be forced unwillingly upon members of the Armed Services. *See, e.g.*, ECF 41-3, Adirim Interchangeability Memo.

Plaintiffs also claimed that the FDA's actions regarding these interchangeable products were *ultra vires* because Congress, under its plenary authority to regulate interstate commerce, has mandated very specific statutory requirements for biologic products to be treated as "interchangeable" in the Public Health Service Act ("PHSA"). Those requirements are mandatory, non-delegable, and non-waivable by the Defendant FDA. *See* ECF 41, ¶¶ 241 – 246. This also includes the FDA's decisions to exercise "its 'enforcement discretion'… not to enforce labeling requirements [including] the requirement to provide the EUA factsheet that includes the 'option to accept or refuse' the EUA vaccine" and thereby "eliminating the statutory right to refuse the unwanted

treatment." *Id.*, ¶ 261. The injuries Plaintiffs allege, therefore, are not confined to just the "bad paper", adverse personnel actions and other career harms, but also consist of the violation of statutory rights to informed consent embodied in multiple federal statutes cited in Plaintiffs' Amended Complaint. Plaintiffs asked for declaratory judgment against both the Defendant FDA and DoD for the *ultra vires* actions of their officials.

THE FIFTH CIRCUIT'S *APTER* DECISION

The *Apter* decisions addressed a complaint filed by three doctors against the FDA over a series of social media posts made by FDA officials regarding Ivermectin. The *Apter* plaintiffs claimed that the FDA's social media posts constituted "medical advice" and were, therefore, *ultra vires* acts outside of the authority of the agency. The doctors claimed that the posts demonized doctors who were legally prescribing Ivermectin and became the basis for adverse medical board actions, adverse employment actions, as well as the basis for pharmacies refusing to fill the doctors' prescriptions. *Apter*, 2023 WL 5664191, at *3.

The doctors asked for a declaratory judgments regarding (a) the social media posts themselves, and (b) the statutory prohibition against the FDA inability engaging in the practice of medicine. The doctors also asked for an injunction to prohibit the FDA "engaging in such actions." *Id.* The doctors relied upon 3 theories of liability against the FDA officials: "(1) the *ultra vires* doctrine via the APA, (2) the *ultra vires* doctrine itself, and (3) the APA itself. The district court rejected all three paths." *Id.*, at *4.

After the district court dismissed the doctors' claims under FRCP 12(b)(1), the doctors appealed to the Fifth Circuit. In *Apter*, the Fifth Circuit clarified the legal standards to be applied to statutory *ultra vires* claims brought under the APA and non-

statutory *ultra vires* claims where plaintiffs allege that federal agency officials have acted outside of the limits of their statutory authority. The Fifth Circuit explained that:

> Section 702 of the APA generally waives the Federal Government's immunity from a suit seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority. When a plaintiff uses the APA to assert a "non-statutory cause of action"—such as an *ultra vires* claim—section 702 contains two separate requirements for establishing a waiver of sovereign immunity. First, the plaintiff must identify some 'agency action' affecting him in a specific way.... The action need not be final. Second, the plaintiff must show that he has been... adversely affected or aggrieved by that action.... To satisfy this second requirement, the plaintiff must establish that the injury he complains of falls within the 'zone of interests' sought to be protected by the statutory provision whose violation forms the legal basis for his complaint.

Apter, 2023 WL 5664191, at *6.

ARGUMENT

I. *APTER'S* APPLICATION TO THE PLAINTIFFS' CASE AT BAR

Joshua Wilson and the rest of the named Plaintiffs before the Court pled five *ultra vires* claims like those pled by the doctors in *Apter*. As noted in opening paragraph of this Motion, and can be seen from Plaintiffs First Amended Complaint, ECF 41 (Counts III-VIII), Plaintiffs have pled non-statutory and statutory *ultra vires* claims under the APA, 5 U.S.C. § 706.

The Plaintiffs' claims against DoD and FDA officials allege what are conceptually opposite sides of the same *ultra vires* coin, although they involve distinct and separate actions of two separate agencies and sets of officials. Plaintiffs detailed this in their Response (ECF 49) to the government's Motion to Dismiss (ECF 45):

> Plaintiffs have pleaded more than sufficient facts for a reasonable factfinder to conclude that the Defendants' combined actions were specifically designed to avoid the informed consent requirements of [10 U.S.C] § 1107a. In order to do so, the Defendants' (a) had FDA

> declare (in a footnote) of a regulatory letter that an unlicensed and licensed product were "close enough," (b) then the SecDef claim that only "fully licensed" products would be used and that he was placing Covid-19 shots on the list of required vaccines for service in the military; and then (c) the FDA completely abrogated its statutory mandate for interchangeable biologics and allowed a DoD official claim that this was sufficient to justify the products being used "interchangeably"[.]

ECF 49, at 19.

Plaintiffs have alleged in their complaint and all of their moving papers that they fall within the "zone of interests" that Congress 'sought to protect' with the passage of 10 U.S.C § 1107a, 21 U.S.C. § 360bbb-3, and the applicable portions of the statutes governing both drugs and biologic products: the Federal Food Drug and Cosmetic Act (21 U.S.C. §301, *et seq*) and the PHSA, 42 U.S.C. § 262. Plaintiffs have also identified discrete actions by officials that "affected" and "aggrieved" them in "specific" ways. ECF 49, at 17-18.

The Fifth Circuit's decision did not allow the doctors' claims regarding the social media posts to proceed on straight APA grounds because:

> [w]hen judicial review is sought pursuant only to the general provisions of the APA, a plaintiff who wishes to establish that there was a waiver of sovereign immunity must show that it has suffered legal wrong because of final agency action. There are two requirements for finality. First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. Second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

Apter, 2023 WL 5664191, at *9.

Unlike social media posts, however, Plaintiff Wilson and his comrades-in-arms complain of final agency actions, such as the DoD Interchangeability Directives, that were published and relied upon by the entire DoD command structure to charge that plaintiffs violated Article 92 of the Uniform Code of Military Justice, Failure to Obey a Lawful Order

or Regulation, for one example. Likewise, the FDA's waivers of mandatory statutory labeling requirements the PHSA's statutory requirements for finding products to be "interchangeable" were final actions from which legal consequences flowed directly down and onto to the Plaintiffs.

This is why all three categories of plaintiffs' claims (Counts III-VIII) involving statutory and non-statutory *ultra vires* claims, as well as plain APA claims, must be reinstated.

II. PLAINTIFFS' *ULTRA VIRES* CLAIMS ARE NOT MOOT.

The September 1 Order dismissed Plaintiffs' First Amended Complaint in its entirety because the Court found that Secretary Austin's January 10, 2023 memorandum rescinding the August 24, 2021 DoD Mandate rendered all of Plaintiffs' claims moot. ECF 61, at 19. While Plaintiffs believe this finding is erroneous as set forth in their response to Defendants' motion to dismiss, *see* ECF 49, at 2-10, the fact remains that the *ultra vires* actions that Plaintiffs challenge and for which the seek reconsideration—the DoD Interchangeability Directives, the FDA Interchangeability Guidance, and the FDA Waivers—have not been rescinded and remain in effect to this day. Whether these actions are deemed to be final agency actions, as Plaintiffs contend, or non-final agency actions as Defendants have claimed, the Fifth Circuit's decision in *Apter* confirms that these actions are reviewable final actions under the APA or non-final actions subject to non-statutory *ultra vires* review.

In the *Apter* case below, similar to here, the district court (S.D. Texas) dismissed the doctors' claims under Rule 12(b)(1). There, the court believed that the plaintiffs lacked standing vice a finding of mootness, but in either case, the Fifth Circuit has clarified that *ultra vires* claims under the APA are viable, live causes of action on their own. Whether

the Defendant DoD has rescinded the original vaccine mandate or not, the actions (and inactions) of officials in both the DoD and FDA are reviewable by this Court. The Defendants' Motion to Dismiss focused entirely on the Plaintiffs as military members, and whether their paperwork has been corrected or not since the mandate was rescinded; but those issues are beside the point. The right to be vindicated is the right of the Plaintiffs as U.S. citizens to have judicial review of the actions of government officials in order to ensure that those officials do not operate outside of the law and to the harm of Plaintiffs, such as (former SSG) Steven Brown. Therefore, the Court must reinstate Counts III-VIII, and review Defendants' *ultra vires* actions pursuant to and in accordance with the intervening change in controlling law as set forth in the Fifth Circuit's decision in *Apter*.

III. CONCLUSION

This Court should grant reconsideration of the September 1 Order; reverse its finding that Counts III-VIII in Plaintiffs' First Amended Complaint are moot; reinstate Counts III-VIII for further proceedings before this Court; grant the motions to intervene that were pending before this Court prior to dismissal; and adopt a modified scheduling order extending the deadlines set forth in the July 14, 2023 Scheduling Order, ECF 57, as appropriate to reflect the delay due to dismissal and the instant motion for reconsideration.

Dated: September 29, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that I have on this day e-filed the foregoing Plaintiffs' Motion for Reconsideration under Rule 59(e) using the CM/ECF system providing service to all counsel of record.

This 29th day of September, 2023.

Respectfully Submitted,

/s/ Dale Saran

Dale Saran